

**REMARKS**

Claim 22 is pending. No new matter has been added.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claim 22 is rejected under 35 U.S.C. § 112, first paragraph. Claim 22 is directed to a method for detecting a symptomatic *Streptococcus pneumoniae* infection in a human subject of age 12 years or less. The Office Action states on page 3 that “under the provisions of 35 U.S.C. § 112, first paragraph, Applicants should have possession, at the time of the invention, of the claimed invention, i.e. a method of detecting a symptomatic *S. pneumoniae* infection in a human subject of age 12 years or less, which method has a degree of specificity and/or sensitivity that is acceptable by those of skill in the art.” The Office Action also states that “from a review of the instant specification, it appears that at the time of the invention, Applicants did not have possession of a detection method that used one or more scrub lines positioned prior to a capture line in the sample flow path, which yielded an art-acceptable test specificity, let alone a test specificity of 90% or better, an increased sensitivity to urine samples from children infected with pneumococci, and false positives due to nasopharyngeal pneumococcal colonization eliminated or minimized.”

To the contrary, Applicants believe that the method of claim 22, which does not require any specificity or sensitivity level, is supported by the present specification. Claim 22 requires detecting a symptomatic *Streptococcus pneumoniae* infection in a human subject of age 12 years or less. Applicants submit that the specification provides support for detecting a symptomatic *Streptococcus pneumoniae* infection, and for providing a useful result, i.e. an indication of a symptomatic *Streptococcus pneumoniae* infection in the subject. For example, Example 3 of the present application demonstrates that performing the claimed method with a scrub line concentration of 0.3 mg/ml detected 87.5% of positive samples, while a scrub line concentration of 0.4 mg/ml detected 83% of positive samples, supporting the claim requirements of detecting a symptomatic *Streptococcus pneumoniae* infection in a human subject of age 12 years or less. These data shows that the claimed method for detecting a symptomatic *Streptococcus pneumoniae* infection in a human subject of age 12 years or less is supported by the specification.

The Examiner has not demonstrated that the detection of, e.g., at least 83% of positive samples, as supported by the specification, does not achieve “a degree of specificity and/or sensitivity that is acceptable by those of skill in the art.” Moreover, the Examiner has not demonstrated that claim 22 requires such a degree of specificity and/or sensitivity. Therefore Applicants believe that claim 22 complies with the written description requirement. Reconsideration and withdrawal of this rejection is respectfully requested.

### **Conclusion**

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted,

Date: December 18, 2009

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